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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/080,140	05/15/1998	PATRICIA A. BILLING-MEDEL	6105.US.P1	9090

23492 7590 05/20/2003

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/20/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/080,140

Applicant(s)
Billing-Medel et al

Examiner
Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-114 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 6, 2003 has been entered.
2. Claims 74, 75, 78, 80, 83, 84, 86, 89, 91 and 93 have been amended. Claims 96-114 have been added. Claims 74-114 are pending and under consideration.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
4. Claims 84 and 85 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 74 and 75. Claim 103 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 96. Claims 108 and 109 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 100 and 101. Claims 113 and 114 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 94 and 95. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
5. The rejection of claims 74-81 and 84-93 under 35 U.S.C. 102(e) as being anticipated by Au-Young et al (US 5,856,136) is withdrawn in light of applicants amendments. The rejection of claims 82, 94 and 95 is maintained for reasons of record. The rejection of newly added claims 96, 100, 101, 103, 104 and 108-114 is made for the same reasons of record.

Claims 82 and 95 are drawn to the polynucleotide encoding SEQ ID NO:25. Claim 94 is drawn to purified polynucleotides encoding SEQ ID NO:25, 26, 27, 28, 29 and degenerate

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coding sequences thereof. Newly added claim 113 is drawn to a purified polynucleotide sequence which code for a protein having an amino acid sequence selected from the group consisting of SEQ ID NO:25, 26, 27, 28, 29 and degenerate coding sequences thereof. Newly added claim 114 is drawn to an isolated polynucleotide sequence which encodes for a protein having an amino acid sequence corresponding to SEQ ID NO:25. Au-Young et al disclose Sequence 4 (nucleotides 7-375 and 214-303, respectively) which encodes the instant SEQ ID NO:25 and the instant SEQ ID NO:28; Sequence 25 (nucleotides 60-161) which encodes the instant SEQ ID NO:26; Sequence 23 (nucleotides 160-282) which encodes the instant SEQ ID NO:27; and Sequence 26 (nucleotides 14-76) which encodes the instant SEQ ID NO:29.

Applicant has not made any amendments or arguments concerning the anticipation of claims 82, 94, 95, 113 or 114 by Au-Young et al.

Claims 100, 108 and 110 are drawn to recombinant expression systems comprising nucleic acid sequences or DNA sequences that include an open-reading frame operable linked to a control sequence compatible with a desired host, wherein said nucleic acid sequence consists of a sequence consisting of SEQ ID NO:3, 4 and 5. Claims 101, 109 and 11 are drawn to a cell transfected with the recombinant expression system of claims 100, 108 and 110, respectively. Au-Young et al disclose purified polynucleotides comprising SEQ ID NO: 4 and 5 vectors, and kits thereof. Au-Young et al disclose Sequence 4 (nucleotides 1-207 and nucleotides 102-366) comprising the instant SEQ ID NO:4 and 5, respectively.

Applicant has attempted to overcome the rejections by amending the claims to read on a recombinant expression system comprising a nucleic acid sequence or a DNA sequence that includes an open reading frame, wherein said nucleic acid sequence or DNA sequence is selected from the group consisting of SEQ ID NO:3, 4 and 5. However, these newly added claims still persist on reading on the sequences disclosed by Au-Young et al. Au-Young et al disclose purified polynucleotides comprising SEQ ID NO: 4 and 5 vectors, and kits thereof. Au-Young et al disclose Sequence 4 (nucleotides 1-207 and nucleotides 102-366) comprising the instant SEQ

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ID NO:4 and 5, respectively. Because the claimed expression system comprises a nucleic acid sequence that includes an open-reading frame, the claim reads on a nucleic acid sequence which comprises an open reading frame. Further, the instant specification discloses SEQ ID NO:4 and 5 as partial cDNA sequences, and as such, said partial DNA sequences are lacking a complete open reading frame. Thus, Au-Young et al disclose a polynucleotide of Sequence 4 comprising an open reading frame, expression vectors and host cells comprising said expression vectors which anticipate the instant claims.

Claims 96, 103 and 104 are drawn to a kit comprising a container containing a polynucleotide sequence selected from the group consisting of SEQ ID NO:3, 4 and 5; claim 112 is drawn to a composition of matter comprising an isolated DNA molecule consisting of a sequence selected from the group consisting of SEQ ID NO:3, 4 and 5. Because claims 96 and 103 recite a kit "comprising" and claim 112 recites a compositions of matter "comprising" the further recitation of "consisting of" is non-limiting. Accordingly, the claims are given the broadest reasonable interpretation of "comprising" and are thus anticipated by Au-Young et al.

6. The rejection of claims 74-81 and 84-93 under 35 U.S.C. 102(e) as being anticipated by Reiter et al (US 6,267,960) is withdrawn in light of applicants amendments. The rejection of newly added claims 96, 100, 101, 103, 104, 108, 109, 110, 111 and 112 is made for the same reasons of record as set forth above.

Reiter et al disclose the purified polynucleotides of Sequence 1, vectors and kits thereof. Reiter et al disclose the polynucleotide comprising the instant SEQ ID NO:3 as residues 10-288 of Sequence 1, SEQ ID NO:4 as residues 12-218 of Sequence 1, and SEQ ID NO:5 as residues 113-377 of Sequence 1. Because the claimed expression system comprises a nucleic acid sequence that "includes" an open-reading frame, the claim reads on a nucleic acid sequence which comprises an open reading frame. Further, the instant specification discloses SEQ ID NO:3, 4

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and 5 as partial cDNA sequences, and as such, said partial DNA sequences are lacking a complete open reading frame. Thus, the instant claims are anticipated by Sequence 1 of Reiter et al.

Claims 96, 103 and 104 are drawn to a kit comprising a container containing a polynucleotide sequence selected from the group consisting of SEQ ID NO:3, 4 and 5; claim 112 is drawn to a composition of matter comprising an isolated DNA molecule consisting of a sequence selected from the group consisting of SEQ ID NO:3, 4 and 5. Because claims 96 and 103 recite a kit “comprising” and claim 112 recites a compositions of matter “comprising” the further recitation of “consisting of” is non-limiting. Accordingly, the claims are given the broadest reasonable interpretation of “comprising” and are thus anticipated by Reiter et al.

7. Claims 78, 79, 89, 90, 91, 92, 100, 101, 108, 109, 110, 111 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 79, 90, 92, 101, 109 and 111 read on a cell within a human and claims 78, 89, 91, 100, 108 and 110 read on a vector within a human. Amendment of the claims to recite “An isolated recombinant expression system” and “An isolated cell” would overcome this rejection.

8. Claims 74-81, 83-93, 96-112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite “degenerate coding sequences thereof” without reference to a protein sequence which is being encoded, as SEQ ID NO:1, 2, 7, 8, 9, 10, 11 and 12 are all polynucleotide sequences.

9. Claims 74-81, 83-93, 96, 100, 101, 103, 104, 108, 109, 110, 111 and 112 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

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specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 74-81, 84-93, 96, 100, 101, 103, 104, 108, 109, 110, 111 and 112 are drawn to polynucleotide sequences comprising the sequence of SEQ ID NO:1, 2, 3, 4, 5, 7, 8, 9 and 10. The specification identifies said sequences as partial EST sequences (page 55, lines 1-12). The specification does not address whether the partial sequences comprise intron/exon splice junctions. When given the broadest reasonable interpretation, the claims can be interpreted as reading on genomic sequences, including any full length gene which comprises each of the sequence. Thus, each EST sequence represents a genus of polynucleotides.

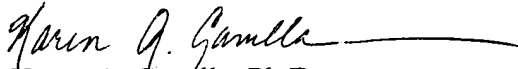
The disclosure of a single species of a genus may provide adequate written description of the genus which the species disclosed is representative of the genus. The present claims encompass full length genes, cosmid and chromosomes comprising said genes. Eukaryotic chromosomes and genes are expected to comprise regulatory regions and untranslated intron regions. These regions are not disclosed by the specification. There is substantial variability among the species of polynucleotides encompassed by the genres because SEQ ID NO:1, 2, 3, 4, 5, 7, 8, 9 and 10 represent only a fragment of any full length gene or chromosome. Functional attributes such as coding capacity cannot be relied upon to distinguish partial sequence from complete genes and chromosomes because complete genes and chromosomes also would encode the sequence which was deduced from the analysis of the combined partial sequences (SEQ ID NO:25). Amendment of the claims to polynucleotide consisting of SEQ ID NO:1, 2, 3, 4, 5, 7, 8, 9 and 10. would overcome this rejection.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be

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left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

May 18, 2003